#### REMARKS

This reply is in response to the Office Action mailed on July 27, 2007 in which claims 1-17 were rejected. Applicant respectfully requests reconsideration of the present application in view of the reasons that follow.

### 1. Examiner Interview Conducted on September 24, 2007

On September 24, 2007, Applicant's attorney conducted a telephone interview with Examiner Koharski during which independent claims 1 and 13 where discussed in light of Sasso et al., U.S. Patent Application Publication No. 2004/0225292. The amendments to claims 1 and 13 are intended to reflect the outcome of the discussion with the Examiner to clearly indicate that the insert fenestration(s) (see claim 1) and permeable section (see claim 13) are located between the two ends of the insert, distinguishing over the structure shown in Sasso et al. Applicant understands that additional searching may be required by the Examiner, and therefore has filed the present amendment along with an RCE. Applicant requests that the Examiner contact Applicant's attorney at the number set forth below regarding the results of such additional searching prior to issuing another office action on the merits.

During the telephone interview, the Examiner brought Margulies et al., U.S. Patent No. 6,679,890, to Applicant's attention. Margulies et al. does not identically disclose an insert having "one or more insert fenestrations disposed along the cannulated portion of the insert between the two ends of the insert" as recited in amended independent claim 1. In addition, Margulies et al. does not identically disclose an insert having "a section between the two ends of the insert that is permeable to the substance to be delivered to the bone" as recited in independent claim 13. In contrast, Margulies et al. discloses an "injection tube 40" having a "continuous hole 44" that results in an aperture in "tube tip 42." See Fig. 1, col. 5, lines 40-42 & col. 6, lines 6-8. Neither the "continuous hole 44" nor the resulting aperture in "tube tip 42" is "one or more insert fenestrations disposed along the cannulated portion of the insert between the two ends of the insert" or "a section between the two ends of the insert that is permeable to the substance to be

delivered to the bone." Further, <u>Margulies et al.</u> discloses "a hollow implant 20" having "a lateral portion 21" and "a medial portion 22" that is a contiguous portion of the "hollow implant 20." <u>See</u> Fig. 1 & col. 4, lines 49-51. The "medial portion 22" is not "an insert disposed inside the cannulated bone-screw shaft" as recited in independent claim 1 and independent claim 13.

# 2. Rejection of Claims 1-2 and 4-9 Under 35 U.S.C. § 102(e) as Anticipated by Sasso et al.

On page 2 of the Office Action, the Examiner rejected claims 1-2 and 4-9 under 35 U.S.C. § 102(e) as anticipated by Sasso et al., U.S. Patent Application Publication No. 2004/0225292. Applicant has amended independent claim 1 to overcome the rejection based on Sasso et al.

In response to the earlier arguments made by Applicant, the Examiner identifies the opening of the "axial passageway 54" at the distal end of "elongate guiding portion 14" of <u>Sasso et al.</u> as an "insert fenestration" as that term is used in independent claim 1. Office Action, page 6. In response, Applicant has amended claim 1 to clarify the distinction between the "insert" of independent claim 1 and the "elongate guiding portion 14" of <u>Sasso et al.</u>

Independent claim 1, as amended, recites that "the insert comprises two ends connected by a shaft" and "one or more insert fenestrations disposed along the cannulated portion of the insert between the two ends of the insert" (emphasis added). Sasso et al. does not identically disclose an insert having "one or more insert fenestrations disposed along the cannulated portion of the insert between the two ends of the insert." In contrast, Sasso et al. only discloses an "elongate guiding portion 14" having an "axial passageway 54" that results in an aperture at the distal tip of "shaped end portion 50" of "elongate guiding portion 14." See Fig. 2, Fig. 3, paragraph [0030] & paragraph [0035]. Neither the "axial passageway 54" nor the resulting aperture in the "shaped end portion 50" is "one or more insert fenestrations disposed along the cannulated portion of the insert between the two ends of the insert" as recited in amended independent claim 1. Applicant's specification identifies a need for the ability to customize the

location of fluid delivery through the bone screw/insert combination. It is the presence of "one or more insert fenestrations disposed along the cannulated portion of the insert between the two ends of the insert" that allows this customization.

In view of the amendments to independent claim 1 and the arguments set forth above, Applicant respectfully asserts that independent claim 1 and corresponding dependent claims 4-9 are not anticipated under 35 U.S.C. § 102(e).

3. Rejection of Claims 13-17 Under 35 U.S.C. § 102(e) as Anticipated by Sasso et al.

On page 2 of the Office Action, the Examiner rejected claims 13-17 under 35 U.S.C. § 102(e) as anticipated by Sasso et al. Applicant has amended independent claim 13 to overcome the rejection of claims 13-17 based on Sasso et al.

In response to earlier arguments made by the applicant, the examiner states that the opening of the "axial passageway 54" at the distal end of "elongate guiding portion 14" of Sasso et al. makes "elongate guiding portion 14" "permeable" as that term is used in independent claim 13. Office Action, page 6. In response, Applicant has amended independent claim 13 to clarify the distinction between the "insert" of independent claim 13 and "elongate guiding portion 14" of Sasso et al.

Independent claim 13, as amended, recites that "the insert comprises two ends connected by a shaft . . . wherein the insert comprises a section between the two ends of the insert that is permeable to the substance to be delivered to the bone" (emphasis added). Sasso et al. does not identically disclose an insert having "a section between the two ends of the insert that is permeable to the substance to be delivered to the bone." In contrast, Sasso et al. only discloses an "elongate guiding portion 14" having an "axial passageway 54" that results in an aperture at the distal tip of "shaped end portion 50" of "elongate guiding portion 14." See Fig. 2, Fig. 3, paragraph [0030] & paragraph [0035]. Neither the "axial passageway 54" nor the resulting

aperture in the "shaped end portion 50" is "a section between the two ends of the insert that is permeable to the substance to be delivered to the bone" as recited in amended claim 13.

In view of the amendments to independent claim 13 and the arguments set forth above, Applicant respectfully asserts that independent claim 13 and corresponding dependent claims 14-17 are not anticipated under 35 U.S.C. § 102(e).

## 4. Rejection of Claim 3 Under 35 U.S.C. § 103(a) Based Upon Sasso et al. in View of Nelson

On page 3 of the Office Action, the Examiner rejected claim 3 under 35 U.S.C. § 103(a) as unpatentable over <u>Sasso et al.</u> in view of <u>Nelson</u>, U.S. Patent No. 5,702,372. As discussed above, independent claim 1 has been amended to overcome the rejection based on <u>Sasso et al.</u> The "lined infusion catheter" of <u>Nelson</u> does not remedy the deficiencies of <u>Sasso et al.</u> The "catheter system 22" of <u>Nelson</u> does not appear to include any insert fenestrations or an insert disposed inside a cannulated bone-screw. <u>See</u> Figs. 2-4. Accordingly, claim 3, which depends from independent claim 1, is presented for reconsideration and allowance.

# 5. Rejection of Claim 10 Under 35 U.S.C. § 103(a) Based Upon Sasso et al. in View of Miller et al.

On page 4 of the Office Action, the Examiner rejected claim 10 under 35 U.S.C. § 103(a) as unpatentable over <u>Sasso et al.</u> in view of <u>Miller et al.</u>, U.S. Patent No. 6,228,088. As discussed above, independent claim 1 has been amended to overcome the rejection based on <u>Sasso et al.</u> The "combination drill bit and intramedullary catheter" of <u>Miller et al.</u> does not remedy the deficiencies of <u>Sasso et al.</u> The "intramedullary catheter 10" of <u>Miller et al.</u> does not appear to include an insert or any insert fenestrations. <u>See</u> Fig. 1. Accordingly, claim 10, which depends from independent claim 1, is presented for reconsideration and allowance.

# 6. Rejection of Claims 11-12 Under 35 U.S.C. § 103(a) Based Upon Sasso et al. in View of Wigness et al.

On page 5 of the Office Action, the Examiner rejected claims 11-12 under 35 U.S.C. § 103(a) as unpatentable over Sasso et al. in view of Wigness et al., U.S. Patent No. 5,203,770. As discussed above, independent claim 1 has been amended to overcome the rejection based on Sasso et al. The "method and apparatus for catheterization" of Wigness et al. does not remedy the deficiencies of Sasso et al. The "cannula arrangement 41" and "tap arrangement 40" of Wigness et al. does not appear to include fenestrations between the two ends of the "internal lumen, bore or flow through channel 42." See col. 7, lines 25-28 & 54-59; Fig. 4; Fig. 5. Accordingly, claims 11-12, which depend from independent claim 1, are presented for reconsideration and allowance.

### 7. Conclusion

Claims 1-17 are pending in the present application. Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date September 26, 2007

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